

**IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF VIRGINIA**

WHOLE WOMAN’S HEALTH ALLIANCE, on
behalf of itself, its staff, and its patients; et al.,

Plaintiffs,

v.

UNITED STATES FOOD AND DRUG
ADMINISTRATION; et al.,

Defendants.

Case No. 3:23-cv-00019-RSB

**PLAINTIFFS’ COMBINED REPLY IN SUPPORT OF PLAINTIFFS’ MOTION FOR
PRELIMINARY INJUNCTION AND OPPOSITION TO DEFENDANTS’ MOTION TO STAY**

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The use of mifepristone is under grave threat in the United States—no party disputes this. And no one disputes that these threats are magnified because the Supreme Court has now allowed states to prohibit abortion entirely.¹ *Dobbs v. Jackson Women’s Health Organization*, 142 S. Ct. 2228, 2284 (2022). The Government spills much ink, however, about how Plaintiffs need to wait until the next time mifepristone is yanked from the market or burdened by outdated restrictions in order to seek parallel relief to that granted by the district court in *Washington v. U.S. Food and Drug Administration*, No. 1:23-cv-3026, 2023 WL 2825861 (E.D. Wash. April 7, 2023) (the “*Washington Case*”). But, neither in its response nor at argument, could the Government justify Plaintiffs being subject to dramatic uncertainty surrounding mifepristone when their colleagues covered by the *Washington* injunction are not. Nor can the Government explain how it is appropriate to allow Plaintiffs’ patients to risk being unable to get mifepristone when patients in 17 states and the District of Columbia do not. It is too late to seek relief when Plaintiffs—small healthcare practices who cannot continue to try to retool their provision of care repeatedly on a dime—are already unable to provide their patients with mifepristone. And, it is too late when patients are already being denied essential healthcare.

In the states covered by the *Washington* injunction, providers are moving ahead with providing mifepristone pursuant to the 2023 REMS without fear.² They are thus insulated from

¹ Abortion is now illegal in 13 states. Another 11 states are extremely hostile to abortion and are severely restricting access to it. Virginia is adjacent to three ban states—West Virginia, Kentucky, and Tennessee—and one state that severely restricts abortion—North Carolina. Montana is adjacent to three ban states—Idaho, North Dakota, and South Dakota—and one that severely restricts abortion—Wyoming. And, Kansas is adjacent to two ban states—Missouri and Oklahoma—and one state that severely restricts abortion—Nebraska. See Center for Reproductive Rights, *After Roe Fell Map*, Abortion Laws by State, <https://reproductiverights.org/maps/abortion-laws-by-state/hts> (last accessed June 14, 2023).

² The Washington court later clarified that its preliminary injunction “was effective as of April 7, 2023 and must be followed by Defendants . . . irrespective of the Northern District of Texas Court ruling or the Fifth Circuit’s anticipated ruling,” given the “circumstances,” and because the Court had “jurisdiction over the parties before it and limited its preliminary injunction” to the plaintiff jurisdictions, and because “a potentially contradictory order out of the Northern District of Texas” was “currently stayed and was not in effect at the time of” the entry of the injunction. *Washington*

further fallout of the injunction issued by the district court in *Alliance for Hippocratic Medicine v. U.S. Food and Drug Administration*, No. 2:22-cv-223, 2023 WL 2825871 (N.D. Tex. April 7, 2023) (the “*Alliance Case*”), or any other regulatory developments. Any further court orders in the *Alliance Case* will be issued against the backdrop of the injunction in the *Washington Case*. Plaintiffs are left out, which is devastating because they and their patients stand to be particularly harmed by roll backs in access to mifepristone.

Plaintiffs have met their burden of demonstrating that the narrow injunction they seek is warranted to protect access to mifepristone in three additional states not subject to the *Washington* injunction, and the Government’s Motion to Stay should be denied.

I. Plaintiffs have demonstrated that a narrow injunction affording Virginians, Montanans, and Kansans the same relief entered in *Washington* is appropriate.

A. The Government incorrectly articulates the legal standard for irreparable injury.

There is no dispute about the four-factor test for a preliminary injunction. *See Di Biase v. SPX Corporation*, 872 F.3d 224, 230 (4th Cir. 2017). Instead, the Government creates a new fifth factor—that Plaintiffs’ irreparable harm track the relief they are seeking on the merits of their ultimate claims. *See* ECF 27, June 5, 2023 Response Brief (“Gov’t Resp.”) at 19. But that new factor is made up out of whole cloth. Courts typically look to the specific irreparable harm a party alleges in declarations in determining whether they are experiencing irreparable harm that can be prevented by an interlocutory injunction. *See, e.g., Seaman v. Virginia*, 593 F.Supp.3d 293, 327 (W.D. Va. 2022). The Government cites five cases for this novel theory, none of which support its position. *See id.* Four of these cases evaluate the appropriate remedy *on the merits*. Gov’t Resp. at

v. U.S. Food and Drug Administration, No. 1:23-cv-3026, 2023 WL 2941567, at *2 (E.D. Wash. April 13, 2023). As a result of the stay issued by the Supreme Court, it is still not in effect.

19 (citing *Bacon v. City of Richmond, Va.*, 475 F.3d 633, 638 (4th Cir. 2007); *Swann v. Charlotte-Mecklenburg Bd. of Ed.*, 402 U.S. 1, 16 (1971); *Lujan v. Nat'l Wildlife Fed'n*, 497 U.S. 871, 891 (1990); *Hill Dermaceuticals, Inc. v. FDA*, 709 F.3d 44, 46 n.1 (D.C. Cir. 2013)). The fifth case cited arises in a separate APA context regarding a challenge to specific agency action withheld. *See id.* (citing *Norton v. Southern Utah Wilderness Alliance*, 542 U.S. 55, 63 (2004)).

To be sure, it is common for a motion for preliminary injunction to seek to temporarily block a policy while the ultimate merits of that policy are litigated. But, a court is not prevented from crafting an injunction that is more narrow than the permanent relief sought on the merits if it will forestall irreparable harm and protect the interests of the parties and its own jurisdiction to resolve the dispute while the case is litigated on the merits. Rather, “[c]rafting a preliminary injunction is an exercise of discretion and judgment, often dependent as much on the equities of a given case as the substance of the legal issues it presents.”³ *Trump v. Int’l Refugee Assistance Project*, 582 U.S. 571, 579 (2017). Interim equitable relief serves “not to conclusively determine the rights of the parties . . . but to balance the equities as the litigation moves forward.” *Id.* (internal citations omitted). In designing such relief, a court “need not grant the total relief sought by the applicant but may mold its decree to meet the exigencies of the particular case.” *Id.*; *see also North Carolina v. Covington*, 581 U.S. 486, 488 (2017) (“A district court therefore must undertake an equitable weighing process to select a fitting remedy for the legal violations it has identified . . . taking account of what is necessary, what is fair, and what is workable.”) (internal quotation marks and citations omitted).

³ Curiously, the Government argues that the *Washington* court entered relief no party had asked for or briefed, Gov’t Resp. at 2-3, but the plaintiffs in that case sought relief “enjoining FDA from reducing mifepristone’s availability,” and that is what the court appears to have ordered, *Washington*, 2023 WL 2825861, at *10 (“Defendants are preliminarily enjoined from altering the status or rights of the parties under the operative Mifepristone REMS Program until a determination on the merits.”).

The Government also incorrectly conflates the determination on whether Plaintiffs have standing to *bring this case* with whether they are entitled to receive the interlocutory *remedy* of a preliminary injunction. The cases the Government cites for conducting a separate standing analysis for a preliminary injunction all address whether plaintiffs have standing to seek their ultimate relief on the merits. *See* Gov’t Resp. at 16-18. Indeed, Plaintiffs must have “standing to seek each form of relief requested *in the complaint*.” *Town of Chester, N.Y. v. Laroe Estates, Inc.*, 581 U.S. 433, 439 (2017) (emphasis added); *accord Carolina Youth Action Project; D.S. by and through Ford v. Wilson*, 60 F.4th 770, 778 (4th Cir. 2023). Plaintiffs clearly have standing to bring this case,⁴ and the Government does not contend otherwise.

The evidence underlying a determination on standing can inform a court’s determination on whether a party is entitled to a preliminary injunction to avert irreparable harm, which is a form of injury in fact. *See Seaman v. Virginia*, 593 F.Supp.3d 293, 327 (W.D. Va. 2022) (“The evidence underlying the Court’s finding that Plaintiffs have established injury in fact and traceability of their injuries for purposes of the Court’s standing inquiry, also supports this Court’s conclusion that Plaintiffs have shown a likelihood of irreparable harm absent injunctive relief.”). But, the question of whether Plaintiffs are entitled to a preliminary injunction is dependent on whether Plaintiffs meet the four-factor standard.

In short, the question for this court to resolve on Plaintiffs’ Motion for a Preliminary Injunction is: do Plaintiffs meet the four-factor standard for the narrow preliminary injunction they

⁴ Plaintiffs are challenging the 2023 REMS, which they allege limit the accessibility of mifepristone by constraining the provider pool, confusing and stigmatizing patients, and making it more difficult to use mail-order pharmacies in direct-to-patient telehealth. *See* Plaintiffs’ Compl. ¶¶ 105-128. Plaintiffs also allege that FDA’s decision to continue to impose a REMS on mifepristone is part and parcel of efforts to restrict mifepristone and treat it as if it is something dangerous, which it is not. *See id.* ¶¶ 4-5, 10, 78, 132. This is clearly an injury in fact. Further, the regulations were promulgated by the Defendants, and relief sought against the 2023 REMS on the merits will redress the wrongs Plaintiffs allege.

seek based on the likelihood of success on the merits of their ultimate claims, the unique irreparable harm they are alleging at this juncture, and in light of the equities and public interest? They do.

B. Plaintiffs are presently experiencing significant irreparable harm that their fellows covered by the *Washington* injunction are not.

The Government does not dispute that Plaintiffs are small healthcare providers who are struggling to adapt their practices to rapid-fire changes in the availability of mifepristone. It does not deny that healthcare has no on/off switch, and that the developments in the *Alliance* case continue to cause uncertainty and chaos for Plaintiffs and the patients they serve. And, it does not suggest how Plaintiffs might be able to weather yet another round of events compromising their ability to prescribe mifepristone—which will result in patients being delayed in obtaining abortion, the denial of access to medication abortion, and outright denial of access to abortion for some. Most importantly, the Government does not address how fundamentally inequitable it is for Plaintiffs and their patients to experience these harms *while providers and patients in 17 states and the District of Columbia do not*. This is especially true given that the *Washington* injunction is to remain in place pending a determination on the merits because the Government did not appeal, nor did it seek to stay that case. These facts are sufficient to warrant a preliminary injunction to protect Plaintiffs’ provision of mifepristone while their challenge to the 2023 REMS—which Plaintiffs allege are ultimately responsible for the stigma that surrounds mifepristone, *see* Plaintiffs’ Compl. ¶¶ 4-5, 10, 78, 132—proceeds on the merits.

The Government merely asserts that the stay in the *Alliance* case has averted (for now) the removal of mifepristone from the market or the reinstatement of burdensome restrictions.⁵ *See*

⁵ It is notable that at argument on May 17, 2023 in the *Alliance* case, the Fifth Circuit panel suggested that the brand name manufacturer of mifepristone, Danco, might only have “several months probably” to prepare labeling for their mifepristone should the Fifth Circuit issue an order that tracks the reasoning of the Fifth Circuit stay decision. *See* May 17, 2023 Argument, *Alliance for Hippocratic Medicine v. U.S. Food and Drug Administration*, 23-10362 (5th

Gov't Resp. at 15, 16, 18, 28. But, it is *the uncertainty* about how Plaintiffs and their patients are to respond to such events that is causing them irreparable harm. The very purpose of a preliminary injunction is to avert such irreparable injuries as being denied essential medical care.

Whole Woman's Health faces particular confusion because it has clinics within and without the scope of the *Washington* injunction—their clinics in Virginia are not subject to the injunction, but their clinics in Minnesota, Maryland, and New Mexico are. Hagstrom Miller Decl. ¶¶ 7, 14. Similarly, their virtual practice provides mifepristone to patients in Virginia, but also in Maryland, Minnesota, New Mexico, and Illinois. Hagstrom Miller Decl. ¶ 20.

Plaintiffs have expended significant resources in order to parse conflicting court orders, pivot their practices, explain the chaos to patients, and ensure that they are providing evidence-based patient care throughout. Hagstrom Miller Decl. ¶¶ 30, 33; Smith Decl. ¶¶ 23-24; Tong Decl. ¶¶ 10, 22-24, 27, 30-32; Weems Decl. ¶¶ 19-24. Trust Women spent \$20,000 on brand name mifepristone that they did not know if they would be able to use, but they cannot keep expending such resources. Tong Decl. ¶ 28.

Plaintiffs' patients have also suffered. Plaintiffs are receiving calls from confused and panicked patients who are not sure if medication abortion even remains available. Hagstrom Miller Decl. ¶ 31; Smith Decl. ¶ 27. Some patients continue to think that medication abortion is banned despite the Texas orders having not taken effect. Hagstrom Miller Decl. ¶ 31.

Plaintiffs need certainty around their provision of mifepristone in order to meet the needs of the thousands of patients traveling from states that have banned abortion in the post-*Dobbs* reality. Hagstrom Miller Decl. ¶¶ 31-32, 38-43; Smith Decl. ¶¶ 28-30; Tong Decl. ¶¶ 16-21; Weems

Cir.), Min.48:50-49:40, ca5.uscourts.gov/OralArgRecordings/23/23-10362_5-17-2023.mp3. This stands contrary to the Government's assertions that Plaintiffs can rely on the Supreme Court indefinitely. *See* Gov't Resp. at 15.

Decl. ¶¶ 31-34. The reinstatement of older pre-2016 restrictions on mifepristone’s use that could bar the use of direct-to-patient telehealth, the ability of advanced practice clinicians to be certified prescribers of the medication, and the use of the generic mifepristone (as the Fifth Circuit decision in the *Alliance* case may cause again) would be nearly as catastrophic as the elimination of the drug altogether. Plaintiffs’ telehealth practices have been instrumental in their ability to meet the increased need. Hagstrom Miller Decl. ¶¶ 32, 38-43; Smith Decl. ¶¶ 29-30; Weems Decl. ¶¶ 31-34. Helen Weems is the only certified prescriber of mifepristone in northwest Montana. Weems Decl. ¶ 25. If she cannot prescribe mifepristone or prescribe it via direct-to-patient telehealth, an entire region of the country will largely lose access overnight. Weems Decl. ¶¶ 25-32.

In sum, Plaintiffs’ declarations make clear that in the post-*Dobbs* world, mifepristone is absolutely essential to their practices and patients, that disruptions in access to mifepristone are devastating, and that they will not continue to be able to withstand sudden changes to their practices, resulting in significant harm to patients.

C. Plaintiffs have demonstrated a likelihood of success for multiple reasons.

The 2023 REMS was approved in the face of the opposition of the entire mainstream medical community, despite the fact that it gravely harms patients, and despite it being unwarranted under the plain language of the FDCA. Plaintiffs have thus demonstrated a likelihood of success on the merits of their claims that the 2023 REMS violates the APA.

1. The Fourth Circuit’s decision in *Mayor of Baltimore v. Azar*, which the Government ignores, confirms Plaintiffs’ strong likelihood of success in demonstrating the 2023 REMS is arbitrary and capricious.

The Government does not even try to square its promulgation of the 2023 REMS with Fourth Circuit precedent requiring an agency to explain its reasoning when it disagrees with the consensus of the mainstream medical community. *Mayor of Baltimore v. Azar*, 973 F.3d 258 (4th Cir. 2020). An agency cannot simply disagree with “every major medical organization in the

country, without more.” *Id.* at 276. The agency was informed of this consensus most recently in the 2022 citizen’s petition filed by the American College of Obstetricians and Gynecologists (“ACOG”), the American Medical Association, and every other preeminent authority on reproductive health in the United States. *See* Plaintiffs’ Compl. Ex. O (2022 ACOG Citizen’s Petition). Indeed, the agency has done less than disagree, it has *simply ignored* in the 2023 REMS the fact that every major medical organization opposes the imposition of any REMS requirements. *Compare id. with* Gov’t Resp. Ex. C (2023 REMS Rationale Memo).

Even if *Mayor of Baltimore* does not clearly dispose of whether the 2023 REMS is likely arbitrary and capricious, the agency’s consideration of the specific pieces of the modification demonstrates how flimsy the rationale is for maintaining the certified prescriber requirement and the patient agreement form and imposing the pharmacy certification requirement.⁶ The agency speculates that it “continue[s] to be concerned that absent” the certified prescriber requirement, “serious and potential fatal complications associated with medical abortion, including missed ectopic pregnancy and heavy bleeding from an incomplete abortion, would not be detected or appropriately managed.” Gov’t Resp. Ex. C (2023 REMS Rationale Memo) at 13. As to the patient agreement form, the agency states that it did not have studies specifically demonstrating the patient agreement form to be unnecessary and speculates that the agreement form enhances informed consent as more providers offer medication abortion. *Id.* at 13-18, 36-37, 40. The rationale for the new pharmacy requirement is even thinner, as it simply states the agency thinks the pharmacy requirement will ensure the REMS are followed and ensure the safe use of the medication. *Id.* at 40-41. But, the well-documented reality as to all three requirements, as attested in ACOG’s 2022

⁶ In contrast, when the agency evaluated the continued imposition of the in-person requirement, it went through a detailed analysis of the relevant studies in order to come to the conclusion that pharmacy dispensing could continue without sacrificing safety or efficacy. Gov’t Resp. Ex. C (2023 REMS Rationale Memo) at 19-36, 38-40.

citizen's petition, is that *none* of them address *any* of the agency's purported concerns, including as to ruling out ectopic pregnancy or gestational age dating (which any reproductive healthcare clinician can do for any patient seeking pregnancy care). Plaintiffs' Compl. Ex. O (2022 ACOG Citizen's Petition) at 11-17.

As the medical community attested, while having no safety benefit whatsoever, these requirements are heavily burdensome on patients and providers, particularly rural patients, and particularly in light of *Dobbs*, increasing political threats to mifepristone, and new data from Canada showing the safety and efficacy of mifepristone without any REMS requirements. *Id.* The agency asserts that the relief the medical community sought in 2022 was not specifically to remove the REMS entirely, *see* Gov't Resp. at 23, but that is contrary to the information actually in the petition, Plaintiffs' Compl. Ex. O (2022 ACOG Citizen's Petition) at 11-17. In any event, it is undisputed that the agency failed to address these concerns when it issued its 2023 REMS, *see* Plaintiffs' Compl. Ex. P (FDA Resp. to 2022 ACOG Citizen's Petition); Gov't Resp. Ex. C (2023 REMS Rationale Memo), as it must, *Mayor of Baltimore*, 973 F.3d at 276.

Although the Government asserts that FDA considered the burdens of the REMS restrictions, Gov't Resp. at 25, FDA expressly "excluded" from its consideration "the logistics of accessing abortion care," including "time to appointment or the distance traveled to obtain care." Gov't Resp. Ex. C (2023 REMS Rationale Memo) at 11-12. There is no discussion in FDA's memo about the REMS reducing medication abortion's availability or deterring providers. Rather, FDA explained that it discarded studies showing the REMS acts as a barrier to patient care. *Id.* at 11 (noting that FDA's analysis "excluded" . . . "[i]nformation from survey studies or qualitative studies that evaluated perspectives on and/or satisfaction with medical abortion procedures from patients, pharmacists, clinic staff, or providers, even if the study assessed REMS ETASUs").

FDA’s argument that it “has found mifepristone to be safe with the REMS requirements” does nothing to show that mifepristone would be unsafe without the 2023 REMS. Gov’t Resp. at 25. FDA cannot rely on the REMS to prove the REMS itself is necessary. And FDA cannot credibly claim a REMS is justified for mifepristone when it has approved a higher dose, daily version of the same drug—Korlym—without a REMS. FDA’s approval of Korlym without a REMS strongly demonstrates the arbitrariness of the agency’s decision-making. *Bracco Diagnostics, Inc. v. Shalala*, 963 F. Supp. 20, 28 (D.D.C. 1997) (“The disparate treatment of functionally indistinguishable products is the essence of the meaning of arbitrary and capricious.”); *Tummino v. Hamburg*, 936 F. Supp. 2d 162, 169 (E.D.N.Y. 2013) (“The standards are the same for aspirin and for contraceptives.”).

2. The REMS is clearly at odds with FDA’s statutory authority.

The government does not deny that FDA did not evaluate whether imposing a REMS generally continues to be appropriate in 2023. Gov’t Resp. at 24-28; *see* Gov’t Resp. Ex. C (2023 REMS Rationale Memo). This is despite the fact that the Government agrees that a REMS with ETASU can only be imposed when “commensurate with a specific serious risk and, considering such risk, ‘not be unduly burdensome on patient access to the drug[,] and . . . to the extent practicable, . . . minimize the burden on the healthcare delivery system[.]’” Gov’t Resp. at 25 (citing 21 U.S.C. § 355-1). As a result, and as the *Washington* court found on a largely identical record, FDA appears to have “failed to consider an important aspect of the problem,” “[e]ven under a deferential review.” *Washington*, 2023 WL 2825861, at *8. The Government asserts that it was only looking at a “modification” of the REMS, Gov’t Resp. at 24-25, but if the agency could avoid determining whether a REMS was appropriate by framing any review as a “modification,” Section 355 would cease to have any meaning. Because mifepristone does not meet the requirements of

the REMS statute, the 2023 REMS is likely in conflict with FDA’s statutory authority and contrary to law.

D. A narrow injunction serves the public interest and is supported by the equities.

Every equitable consideration available for the Court to take into account weighs in favor of granting the narrow injunction Plaintiffs seek, contrary to the Government’s conclusory objections. *See* Gov’t Resp. at 28-29.

The Government’s, the public’s, and Plaintiffs’ interests are all aligned in protecting the public health and ensuring certainty around access to an essential medication that is foundational to people’s health and dignity. As the Government stated in the *Alliance* case when arguing that deprivation of mifepristone imposes irreparable harm on patients:

For many patients, mifepristone is the best method to lawfully terminate their pregnancies. They may choose mifepristone over surgical abortion for reasons such as medical necessity or past trauma. Surgical abortion is an invasive medical procedure that may have greater health risks for some patients, such as those who are allergic to anesthesia. Surgical abortion is also often unavailable for practical reasons even when abortion is lawful, and travel costs could place abortion entirely out of reach for some patients.

Gov’t Br. at 63-63, *Alliance for Hippocratic Medicine v. FDA*, 2023 WL 3273780 (5th Cir. Apr. 26, 2023). Forcing Plaintiffs’ patients to experience the risk of not being able to get mifepristone, especially when patients covered by the *Washington* injunction do not, serves no one. And, Plaintiffs and their patients should not have to wait to receive certainty until the worst has already happened. As the Washington court held, “[b]ased on the public health and administrative considerations at issue. . . the balance of the equities” and “the public interest” “sharply tip” in favor of a preliminary injunction ensuring certainty in access to mifepristone. *Washington*, 2023 WL 2825861 at *9.

The government asserts that Plaintiffs have shown less harm here than the *Washington* plaintiffs. Gov’t Resp. at 2-3. But, the reverse is true—we have now seen what awaits Plaintiffs

and their provision of mifepristone absent an injunction, whereas there was no *Alliance* order yet when the *Washington* court entered its injunction.

Further, the Government and the public have an interest in equity of federal law between different entities and reliance on federal law. Indeed, the Government attested that “[a]ttempting to adjust the regulatory scheme during the pendency of further litigation . . . would impose substantial costs.” Gov’t Br. at 63-63, *Alliance for Hippocratic Medicine v. FDA*, 2023 WL 3273780 (5th Cir. Apr. 26, 2023). Thus, it is in both Plaintiffs’ and the Government’s interest to insulate Plaintiffs from further uncertainty around their provision of mifepristone along with the jurisdictions covered by the *Washington* injunction. And, far from requiring FDA to litigate on two fronts, Gov’t Resp. at 32, an injunction would simply expand one of the two fronts the agency *already faces*, while ensuring that Plaintiffs have the same protections afforded to other providers.

E. State-wide relief is appropriate.

State-wide relief in Virginia, Montana, and Kansas is appropriately tailored to address the irreparable harm Plaintiffs and their patients are experiencing. It has always been the case that abortion clinics suing on behalf of patients seeking abortion have had standing to challenge actions that affect all people in their state even if not every abortion clinic in the state joins the suit. *See, e.g., Dobbs*, 142 S.Ct. at 2284. Clearly the relief necessary to avoid the irreparable harm to all Virginians, Montanans, Kansans, and others seeking abortion in these three states must be state-wide.

Further, it would be impracticable for relief only to be entered as to Plaintiffs. As the Fourth Circuit noted in *Mayor of Baltimore*, if relief is only entered as to some providers, and other providers experience uncertainty around their provision of care, Plaintiffs will be the only providers not subject to that harm and will experience a huge increase in people seeking care. 973 F.3d at 294 (“[W]ithout the statewide injunction, a Virginia woman seeking an abortion referral

would be obliged to travel to a Title X provider in Baltimore. By contrast, with the statewide injunction, she could obtain a referral from a Maryland Title X provider located closer to the Virginia–Maryland border.”). Entering state-wide relief is thus appropriate to remedy the harm that people seeking abortion in these three states experience.

II. This case is not a collateral attack on the *Alliance* orders.

The Government does not assert that Plaintiffs lack standing to bring their claims on the merits. The Government does suggest that Plaintiffs lack standing because they are seeking to collaterally attack the *Alliance* case, but this reflects a misunderstanding about that doctrine. The “collateral attack” doctrine precludes litigants from collaterally attacking the *judgments of other courts*. Collateral attack on judgments, 21A Fed. Proc., L. Ed. § 51:221. Plaintiffs are not attacking the judgment of another court; they are seeking certainty around the provision of mifepristone in light of the fact that 17 other states and the District of Columbia are so insulated. Indeed, the *Alliance* orders are not judgments. Further, “the general rule . . . is that a civil decree cannot be collaterally attacked *by a party or by a person in privity with a party.*” *U.S. v. City of Chicago*, 870 F.2d 1256, 1260 (7th Cir. 1989) (emphasis added). Plaintiffs are entitled to their day in court to protect their interests, as they are not party to any judgment contrary to the injunction they seek.

The Government points to *Vapor Technology Association v. U.S. Food and Drug Administration* as suggesting that Plaintiffs are running afoul of this doctrine, but that case does not support this. There, the plaintiffs were complaining of a *judgement* entered by a court to impose a deadline for regulatory action. *Vapor Technology Association v. United States Food and Drug Administration*, 977 F.3d 496, 497 (6th Cir. 2020). The plaintiffs there were seeking to attack the deadline the court ordered. Here, Plaintiffs are not asking the court to rule that any order in the *Alliance* case or anywhere else is wrong. They are seeking a narrow preliminary injunction to

afford them the same protection as the *Washington* plaintiffs enjoy to preserve their and their patients' interests.

III. Exhaustion is futile.

Plaintiffs have shown that exhaustion is futile. The government asserts that three things cited by Plaintiffs were not before the agency—studies published in 2022, including Canadian data, the impact of *Dobbs*, and the particular harms of the three requirements ultimately promulgated in 2023, including the pharmacy certification requirement. *See* Gov't Resp. at 25-26. This is incorrect. ACOG's 2022 citizen's petition provided all three and reiterated what the medical community has told FDA over and over—that the REMS are not medically justified and considerably harm patients and providers. *See* Plaintiffs' Compl. Ex. O (2022 ACOG Citizen's Petition) at 11-17. The Government splits hairs in arguing that the 2022 petition was targeted at miscarriage management. But, the standard for futility is not whether someone has asked the exact question raised in the suit; the standard asks whether "an administrative agency has taken a hard and fast position that makes an adverse ruling a certainty." *Thetford Props. IV Ltd. v. Dep't of Hous. & Urban Dev.*, 907 F.2d 445, 448 (4th Cir. 1990). The precise evidence the government says it could not have considered, was before it when it rejected the 2022 ACOG citizen's petition *on the same day* it issued the 2023 REMS. *See* Plaintiffs Compl. Ex. P (FDA Response to 2022 ACOG Citizen's Petition); Gov't Resp. Ex. K (2023 Supplemental Mifepristone Approval). Further, in 2020, fifteen states asked FDA to eliminate the REMS patient agreement and certification requirements as "onerous and medically unnecessary" and received a form response from FDA. *Washington*, 2023 WL 2825861, at *6. The agency thus cannot "credibly" contend that were Plaintiffs to provide this information to the agency again, it would come to a different conclusion. *Id.*

IV. A stay of proceedings is inappropriate.

The Government offers two reasons to stay this case, even though it has not sought a stay or appealed in the *Washington* case, neither of which are persuasive.⁷ A party seeking a stay of proceedings in a suit must make a clear case of hardship in being required to go forward if there is a possibility that the non-moving party will suffer. *Landis v. N. Am. Co.*, 299 U.S. 248, 254-55 (1936); *see also Williford v. Armstrong World Indus. Inc.*, 715 F.2d 124, 127 (4th Cir. 1983). In deciding a motion to stay, “courts of this Circuit have considered factors such as: (1) the interests of judicial economy; (2) potential hardship of the moving party if the action is not stayed; and (3) potential prejudice to the non-moving party.” *Travco Insurance Company v. Ward*, 2010 WL 11570117, at *1 (E.D. Va., 2010).

First, the Government suggests that the Supreme Court’s action on a certiorari petition that may be filed in the *Alliance* case could offer guidance to this court. But, the *Alliance* case is ultimately a challenge to the 2000 FDA approval of mifepristone, and while there are similar questions of fact across the cases, it is not assured that the Supreme Court will say anything about whether the 2023 REMS modification was unlawful. In any event, should the Court grant a certiorari petition in that case, it will be regarding the propriety of entering *preliminary* relief, and is unlikely to conclusively determine any issues, much less issues that will dispose of this case. As a result, a stay does not serve the interests of judicial economy.

Second, the Government incorrectly asserts that Plaintiffs and their patients will not be harmed by a stay of proceedings and that the balance of hardships tips in the Government’s favor. But, this is largely because the Government does not think that the present uncertainty hanging

⁷ At most, the concerns the Government raises go to whether the Preliminary Injunction Motion should be decided now. Should the Court decide to stay proceedings to any degree, such a stay should only go toward consideration of that motion, not the proceedings entirely.

over Plaintiffs and people seeking abortion in Virginia, Montana, and Kansas is irreparable harm—it is, as described *supra* at 5-7. The Government further suggests Plaintiffs will not experience harm because two of the 2023 REMS requirements have been in effect for a long period. *See* Gov’t Resp. at 31. But, as Plaintiffs have explained, and as the agency was informed by the 2022 ACOG citizen’s petition, people seeking abortion and the providers who care for them are facing unprecedented challenges in the wake of the overturning of *Roe* that has made these requirements intolerable. As the *Washington* states attested, “they did not know FDA would approve the 2023 REMS in light of the *Dobbs* decision.” *Washington*, 2023 WL 2825861, at *8. That plaintiffs are not pharmacies makes no difference as to the pharmacy certification requirement because they have stated how they are harmed by being forced to use a small pool of special pharmacies.

Finally, the Government will not experience any “hardship or inequity,” as to being “forced to litigate on [at least] two fronts,” Gov’t Resp. at 32, because they are *already* subject that circumstance. Rather, it is Plaintiffs and their patients who are facing the deep inequity of being excluded from the protection afforded to their counterparts in other states. The Government cannot assert that it would suffer any harm by treating Plaintiffs in the same manner as it is already required to treat the plaintiffs in the *Washington* Case.

For these reasons, this is not the “rare case[],” in which a “litigant” can “be forced to step aside and wait to have his rights settled by a party in a separate action.” *Landis*, 299 U.S. at 254-55.

The Court should grant a preliminary injunction enjoining the Defendants from altering the status quo with respect to the 2023 REMS in the states of Virginia, Montana, and Kansas as it

relates to the availability of mifepristone during the pendency of this litigation and deny Defendants' Motion to Stay.

Dated: June 15, 2023

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on this 15th day of June, 2023, I filed the foregoing document with the Clerk of Court using the CM/ECF system.

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